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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,440	07/13/2006	Bruno Colin	125670	1428

25944 7590 09/19/2008

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,440	COLIN ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The request for reconsideration filed 13 June 2008 has been received. Claims 1-3 are pending.

Claim Rejections - 35 USC § 112

2. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 use unconventional claim language and are vague as to the different limitation of the reaction module.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Thieme (US 5,714,341).

Thieme discloses a device for collecting saliva. The device comprises a chromogenic substrate that interacts with the sample to produce a color product. A level of color above a selected threshold indicates that an effective volume of saliva has been collected. See column 4, lines 13-19 and column 8, lines 15-25.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al (US 5,714,341) in view of Ertinghausen (US 5,087,556).

Thieme differs from the instant claims in failing to teach a graduated scale along the test strip. Thieme also fail to teach a colorimetric pellet.

Ertinghausen discloses a device (i.e. reaction module) comprising a reservoir (reaction well) for receiving test sample. The device further comprises a channel which draws the biological fluid from the first reservoir to a second reservoir through a membrane provided in a channel between the first and second reservoir. The membrane comprises a chromatic chemical indicator in a calibrated or determined concentration. A scale is provided along the channel to readily equate the colored portion in the channel to the concentration of analyte. See column 3, lines 30-58.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ertinghausen to include a scale along the test strip as taught by Ertinghausen because the use of calibrated scales is well known in the art. A skilled artisan would have had a reasonable expectation of success in modify the test strip taught by Thieme with a scale as taught by Ertinghausen because it provides the advantage of a self-contained device that enables a visual indicator of the amount of sample collected.

Even though Thieme does not disclose a colorimetric pellet, Thieme does teach the use of a colorimetric solution. A skilled artisan would have had a reasonable expectation of success choosing either a pellet or a solution as determined by the availability of the material. Furthermore, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Since Applicant has not disclosed that the colorimetric pellet recited in instant claim is for any particular purpose or solve any stated problem and the prior art teaches that a free standing solution or one dried onto a substrate pad appear to work equally as well, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum

workable forms of the product disclosed by the prior art by normal optimization procedures known in the art.

Response to Arguments

7. Applicant's arguments filed 13 June 2008 have been fully considered but they are not persuasive.

Applicant argues that the claim language is not vague because the specification defines the reaction module such that one of ordinary skill in the art would clearly understand the meaning of a reaction module as used in the instant claim.

This argument is not persuasive. Claims are given their broadest reasonable interpretation in light of and consistent with the written description, however, limitations in the specification are not read into the claims. In the instant case, the "reaction module comprising at least one well" could mean a test strip comprising a well; or it could mean an ELIZA plates. As such, the claim is vague with respect to the precise nature of the "reaction module". Additionally, the control means recited in claim 1, for example, is a calibrated colorimetric strip, in the event that the reaction module is an ELIZA plates, where is the calibrated colorimetric strip disposed? How does the colorimetric strip "control" the quantity of biological fluid injected into the well? At best, the colorimetric strip indicates how much fluid has been injected, but to "control" appear to be the ability to stop such an injection of fluid. How does the colorimetric strip perform this function.

The argument with respect to the Thieme and Ertinghausen references is not persuasive. Applicant argues that neither Thieme nor Ertinghausen teach a reaction module as recited in

claims 1 and 3. Applicant argues that as disclosed on page 3 of the specification, the reaction module is a device capable of being inserted into an automated device in order to carry out a biological reaction. These arguments are not persuasive. As stated above, although the claims are interpreted in light of the specification, limitations in the specification are not read into the claims. The reaction module recited in claims 1 and 2 is a device with a well for receiving a sample and a control means in the form of a calibrated colorimetric strip. This module could be anything and is not limited to a "device capable of being inserted into an automated device". Thieme teaches such a device. Thieme teaches a device for collecting saliva comprising a chromogenic substrate that interacts with the sample to produce a color product. A level of color above a selected threshold indicates that an effective amount of saliva has been collected. Furthermore, the device of Thieme is certainly "capable" of being inserted in to an automated device since this too, is vague.

The argument that Ertinghausen does not teach a reaction module capable of being inserted into an automated device is not persuasive for the same reason above. Furthermore, Ertinghausen is cited for its teaching of a graduated scale along the strip for visual determination of the volume of sample collected.

Conclusion

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
17 September 2008